

Appl. No.: 09/980,193
Group Art Unit: 1651
Applicants' Reply to the Office Action dated May 5, 2004

REMARKS

Claims 12-35 are currently pending in the present application.

It is noted that the Office Action Summary, Form PTOL-326, attached to the Office Action indicates that *claims 22-35 have been withdrawn and claims 12-23 have been rejected*. It is respectfully submitted that this is incorrect and should be corrected in the Examiner's next communication. Claims 12-22 have been elected and rejected by the Examiner, and claims 23-35 should be withdrawn from consideration as non-elected.

In the Office Action, the Examiner rejects claims 12-15 under 35 U.S.C. §102(b), as being anticipated by U.S. Pat. No. 5,372,943 of Inlow, *et al.* (hereinafter referred to as "Inlow"). Specifically, citing Examples 2, 8 and 9 of Inlow, the Examiner contends that Inlow "discloses a reaction medium comprising a microemulsion and the microorganisms insect cells, which is identical to the presently claimed composition since the size distribution overlaps and it contains the same ingredients." (See, the Office Action, p. 3). On this basis, the Examiner argues that the claims are anticipated.

Applicants respectfully traverse the Examiner's rejection, along with the contentions and arguments in support thereof for the following reasons.

The rejected embodiments of Applicants' claimed invention are directed to fermentation process reaction mediums which comprise:

- (a) a microorganism; and
- (b) a phase inversion temperature emulsion, *wherein the emulsion comprises water, an emulsifier and an oil phase selected from the group consisting of (i) fatty acid alkyl esters, vegetable triglycerides, and mixtures thereof*, and wherein the emulsion has an average droplet size of from 50 to 400 nm.

In order for a rejection under 35 U.S.C. §102(b) to be proper, each and every element of the claimed invention must be taught, either expressly or inherently, in a single prior art reference. (See, *e.g.*, M.P.E.P. §2131).

Inlow discloses microemulsions containing lipids for use in delivering lipid nutrients to cells in cell culture mediums. (See, Inlow, abstract). However, Inlow does NOT

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disclose reaction mediums containing emulsions comprising *an oil phase selected from the group consisting of (i) fatty acid alkyl esters, vegetable triglycerides, and mixtures thereof*. None of the components of the lipid microemulsion disclosed in Example 2 of Inlow is a fatty acid alkyl ester or a vegetable triglyceride. The microemulsion disclosed in Example 2 of Inlow contains monothiolglycerol, linoleic acid, lecithin, cholesterol, α -tocopherol acetate, and Tween® 80. None of these components is a fatty acid alkyl ester or a vegetable triglyceride.

Moreover, the particle sizes disclosed in Example 9 of Inlow, namely 9 nm, 95 nm and 890 nm, refer to the entire set of components contained in the culture medium prepared in Examples 8 and 9, namely a cell line, insulin, transferrin, selenium, glutamine, and ethanolamine. (See, Inlow, col. 18, lines 60-65 and col. 18, lines 38-44). Thus, it is impossible to say with any certainty that the emulsion prepared in Example 2 has any one particular size in light of the many other components of the culture medium subjected to light scattering measurement. Lastly, Inlow specifically refers to "lipids with the particle size distribution observed, particularly those over 800 nm, . . . it is thought that the microemulsion . . ." (See, Inlow, col. 19, lines 4-9). Inlow appears to specifically recognize a microemulsion particle size much larger than the claimed range of from 50 to 400 nm.

Despite the Examiner's comments regarding the "product-by-process" nature of the emulsion element of the claimed invention, such language has no bearing in this matter. Inlow simply fails to teach the claimed emulsion components and particle size, regardless of how the emulsion is prepared.

Finally, even foregoing any of the arguments set forth above, the Examiner plainly admits later in the Office Action, with respect to the rejection under §103(a), that the Inlow reference fails to teach the use of fatty acid alkyl esters in the medium. (See, the Office Action, p. 3).

Accordingly, Applicants respectfully submit that Inlow can not be held to anticipate the claimed invention which is directed to reaction mediums containing emulsions comprising an oil phase selected from the group consisting of (i) fatty acid alkyl esters, vegetable triglycerides, and mixtures thereof, and having an average droplet size of from 50 to 400 nm.

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Thus, reconsideration and withdrawal of the rejection of claims 12-15 under 35 U.S.C. §102(b), based on Inlow, are respectfully requested.

In the Office Action, the Examiner also rejects claims 12-22 under 35 U.S.C. §103(a), as being unpatentable over Inlow, in view of German Patent Publication No. DE3738812 of Kopp-Holtwiesche (hereinafter referred to as "Kopp-Holtwiesche") and PCT Publication No. WO95/11660 of Förster (hereinafter referred to as "Förster"). Specifically, the Examiner contends that Inlow discloses a reaction medium containing a microemulsion which contains the claimed ingredients, yet the Examiner acknowledges that Inlow fails to teach the use of fatty acid alkyl esters. The Examiner further contends that Kopp-Holtwiesche discloses "a similar reaction medium" containing methyl laurate. Finally, the Examiner notes that Förster discloses the use of a variety of triglycerides for producing various emulsions.

On these bases the Examiner argues that the claims are obvious. Applicants strenuously, but respectfully, traverse the Examiner's rejection and the arguments and contentions in support thereof for the following reasons.

In order to establish *prima facie* obviousness, and thus shift the burden of proving non-obviousness onto Applicants, the Examiner must show all of the following three criteria: (1) there must be some suggestion or motivation to modify or combine the references as suggested by the Examiner (it is not sufficient to say that the cited references can be combined or modified without a teaching in the prior art to suggest the desirability of the modification); (2) there must also be a reasonable expectation of success; and (3) the references as combined must collectively teach or suggest all limitations of the claims. The teaching or suggestion to combine and modify the cited art and the reasonable expectation of success must both be found in the prior art and not in the Applicant's Specification. (M.P.E.P. §2143).

As mentioned above, Inlow fails to teach the claimed emulsion components. The Examiner seemingly admits that Inlow fails to teach either fatty acid alkyl esters or vegetable triglycerides. Inlow also fails to suggest the use of such components as the oil phase of an emulsion for use in a fermentation process reaction medium.

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Neither Kopp-Holtwiesche nor Förster alleviates this deficiency of Inlow. Kopp-Holtwiesche is directed to the use of particular strains of *Candida tropicalis* for the conversion of lauric acid methyl esters to dodecanoic acid. The methyl laurate (fatty acid alkyl ester) is not part of any emulsion used in the reaction medium. The methyl laurate is a substrate for oxidation via the *Candida* species. One of ordinary skill in the art would have no reason to add the methyl laurate oxidation substrate of Kopp-Holtwiesche to the lipid-delivering emulsion of Inlow. Förster is directed in general to oil-in-water emulsions. However, nowhere does Förster specifically teach or even suggest the use of fatty acid alkyl esters or vegetable triglycerides as oil components for emulsions to be used as fermentation process reaction mediums.

Inlow is directed to, and very much concerned with, the delivery of lipid nutrients to cells in a culture medium. Thus, Inlow focuses on special microemulsions for delivering such lipid nutrients. It is not reasonable to argue that one of ordinary skill in the art would, in contradiction to the express teachings of Inlow, alter the reference's teachings by selecting a completely different oil phase emulsion component from a reference unconcerned with lipid nutrient delivery, namely Kopp-Holtwiesche which is directed to fatty acid ester bacterial oxidation. Additionally, the broad general teachings of Förster directed to multiple possible emulsion components can not be said to provide any suggestion to use the specific claimed types of oil phase components in a fermentation reaction medium.

Given the lack of a teaching or suggestion of each and every element of the claimed invention in Inlow, Kopp-Holtwiesche and Förster, and given that none of the references suggests their combination and modification as suggested by the Examiner, it is untenable to assert that a reasonable expectation would exist in the mind of one of ordinary skill in the art based on the cited art.

Accordingly, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness as none of the three criteria for establishing *prima facie* obviousness has been satisfied. Reconsideration and withdrawal of the rejection under §103(a) are respectfully requested.

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In view of the comments set forth above, Applicants submit that all pending claims patentably distinguish over the prior art of record and known to Applicants, either alone or in combination. Accordingly, reconsideration, withdrawal of the rejection and a Notice of Allowance for all pending claims are respectfully requested.

Respectfully submitted,

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(Date)

By: _____

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